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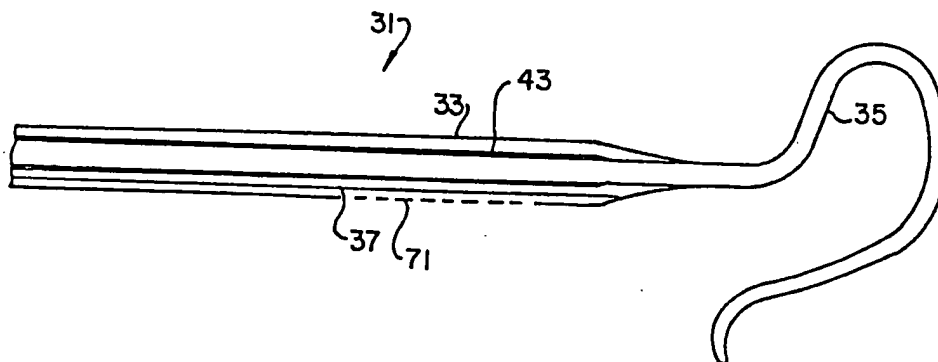
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(54) Title: TRANSFORMABLE CATHETER



(57) Abstract

A medical tube (31) has at least one wire (37) running from the proximal end to the vicinity of the distal end, which wire (37) is connected to the tube adjacent the distal end so as to allow the distal tip to be deflected upon movement of the wire. The tube has gaps (71) therein on one side as to form a predetermined region of weakness, whereby upon tension being applied to the wire (37) the distal end of the tube bends in the direction of the predetermined region of weakness. The medical tube may be a sheath (33) in which is disposed a preformed inner catheter (35) having a complex curve formed into the distal end thereof. By suitable manipulation of the wire (37) and of the inner catheter (35) with respect to the sheath (33) the shape of the exposed portion of the distal end of the inner catheter may be transformed to a variety of shapes.

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Transformable Catheter

Background of the Invention

This invention relates generally to medical devices, and more particularly to a catheter which can be formed, inside the human body, into a vast number of different shapes.

Selective catheterization of cerebral and visceral branch arteries is often difficult and at times impossible in some patients -- particularly older patients with very tortuous and ectatic vasculature. Successful catheterization sometimes requires multiple catheter exchanges for various shaped catheters. It is not uncommon to easily catheterize three of four vessels for a four vessel head study, only to find that the fourth vessel (generally the left or right carotid) requires an entirely different catheter shape and tip orientation. It would be desirable if one could easily and simply reshape the catheter and reorient the tip to direct it into the vessel orifice, instead of depending on several complex catheters that require reformation, fancy torque and advancing maneuvers, body english and, above all, luck.

Tip reorientation, the goal of most prior devices which have addressed the problem, is only half of what is needed to make a truly workable universal catheter. Numerous catheter curve configurations have been conceived not only to reorient the tip properly for selection of branch vessels, but also to provide anchorage of the catheter against the aortic wall. A wide looped long tipped sidewinder III configuration with an exaggerated retrocurve is one such example of a highly specialized complex catheter.

This anchorage or wedge effect against the aortic wall lessens the recoil caused by the "jet effect" during high pressure contrast injection which might otherwise cause the catheter to flip out of the selected branch vessel (particularly in short branch vessels or at levels of a dilated aorta).

These complex configurations, therefore, evolved not only to orient the tip properly, but also to wedge the catheter securely in the branch vessel. Other devices which simply modify the distal catheter curve may aid in tip orientation for vessel

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selection, but fail to provide the anchorage which is necessary to prevent catheter dislodgement.

In addition, prior designs could be improved in that the radii which the prior devices are able to make (to enter a vessel at a sharp angle, for example) have heretofore been severely limited.

Moreover, the size of prior designs has made them less desirable for many applications.

In certain applications (for example, complex interventional procedures such as angioplasties or intracerebral procedures), current catheters could be improved with respect to their ability to facilitate crossing of tight stenoses or with respect to their trackability out into peripheral branches.

In this respect, the current catheters could be improved in the areas of displacing forces from the application site at the point of catheter introduction (most often in the inguinal area) to points close to the actual catheter tip. This would increase the control that a user, such as an angiographer, has on the catheter, creating a more precise local longitudinal vector force for crossing tight stenoses, and also increase torque force for guiding the catheter tip toward the orifice of a selected vessel.

It would also be desirable to have a catheter construction which provided controllable variability in the distal catheter stiffness. Such a catheter could be stiffened for support close to a first order selected branch through which a more flexible catheter could be tracked peripherally. Conversely, such a catheter could be made less stiff over variable distances to allow better tracking of a more flexible distal end over a guidewire.

Summary of the Invention

Among the various objects and features of the present invention may be noted the provision of a catheter which simplifies the catheterization procedure.

A second object is the provision of such a catheter which significantly reduces the number of catheterizations required for any particular medical procedure.

A third object is the provision of such a catheter which can be easily and simply reshaped into a variety of different shapes as desired by the user.

A fourth object is the provision of such a catheter which can mimic almost any catheter configuration, and can thereafter be reformed in the body to other desired shapes.

A fifth object is the provision of such a catheter which obviates the need for multiple catheter exchanges, thereby reducing the time involved in a medical procedure and also reducing the possibility of complications.

A sixth object is the provision of such a catheter which provides adequate anchorage of the catheter against the aortic wall to reduce the "jet effect."

A seventh object is the provision of such a catheter which is capable of achieving an improved curve radius at its distal end.

An eighth object is the provision of such a catheter which is significantly reduced in size compared to the prior devices.

A ninth object is the provision of such a catheter which will displace longitudinal vector force from the site of application in the groin of the patient to a point near the tip of the catheter, thereby facilitating the crossing of tight stenoses during angioplasty procedures.

A tenth object is the provision of such a catheter which will displace torque force from the site of application in the groin of the patient to a point near the tip to facilitate more precise torque of the catheter tip, improving the ability to enter selected vessels.

An eleventh object is the provision of such a catheter which will provide variable stiffness at the distal end that will facilitate catheter advancement peripherally when it serves as a stiffened support near a first order take off vessel and will likewise facilitate tracking over a guidewire when made more flexible over a variable distance, distally.

Other objects will be in part apparent and in part pointed out hereinafter.

Briefly, a catheter of the present invention includes a catheter tube having a wall and an internal lumen extending substantially through the length of the catheter tube, the catheter tube having an outside diameter sufficiently small so that the catheter tube may be inserted into the human body and having a proximal end and a distal end. At least one wire runs from the proximal end of the catheter tube to the vicinity of the distal end of the catheter tube, which wire is connected to the catheter tube adjacent the distal end so as to allow the distal tip of the catheter tube to be deflected upon movement of the wire. The catheter tube has a substantially uniform transverse cross section throughout a substantial part of its length, and the catheter tube wall adjacent the distal end of the catheter tube has gaps therein on one side of the longitudinal axis of the catheter tube so as to form a predetermined region of weakness. Upon tension being applied to the wire, the distal end of the catheter tube bends in the direction of the predetermined region of weakness.

In a second aspect of the present invention, a transformable catheter includes a sheath having a diameter sufficiently small so that the sheath may be inserted into blood vessels of the human body, the sheath having a length which is a substantial fraction of the entire length of the transformable catheter. The sheath also has a bore therethrough running substantially from the proximal end of the sheath to the distal end of the sheath. A preformed inner catheter has a complex curve formed into the distal end thereof, and is sized to fit in the sheath bore. The inner catheter is axially movable with respect to the sheath in the bore, the sheath being sufficiently rigid and the inner catheter being sufficiently pliable so that withdrawal of the inner catheter into the sheath substantially straightens out the portion of the complex curve of the distal tip contained within the sheath. The distal tip resumes its complex curve shape upon movement thereof out of the sheath bore. The user axially moves the inner catheter with respect to the bore to expose only so much of the distal end of the inner catheter as to cause the

exposed portion of the distal end of the inner catheter to take a desired shape. The inner catheter has a length substantially corresponding to the length of the transformable catheter. At least one wire runs from the proximal end of the sheath to the vicinity of the distal end of the sheath, the wire being connected to the sheath adjacent the distal end so as to allow the distal tip of the sheath to be deflected upon movement of the wire. By suitable manipulation of the wire and of the inner catheter with respect to the sheath, the shape of the exposed portion of the distal end of the inner catheter may be reformed and transformed to any of a variety of shapes as desired by the user. The sheath has at its distal end a predetermined region of weakness so that upon tension being applied to the wire, the distal end of the sheath bends in the direction of the predetermined region of weakness.

Although the invention is described in connection with blood vessels, it is not so limited. It may be used not only in arterial and venous branches, but also in the biliary tree, urinary tract, body cavities (such as the thorax and abdomen), hollow viscous organs (such as the stomach, intestines, and urinary bladder), cysts and abscesses -- in short, in any place where selective direction and reformation of a catheter, tube or guidewire is required.

The method of the present invention includes changing the shape of a catheter in a human body. It includes the steps of inserting a combination catheter into a cavity of a human body. The combination catheter has a sheath with a length which is a substantial fraction of the entire length of the combination catheter. The combination catheter also has a preformed inner catheter with a complex curve formed into the distal end thereof disposed in the bore of the sheath. The user axially moves the inner catheter with respect to the bore to expose only so much of the distal end of the inner catheter as to cause the exposed portion of the distal end of the inner catheter to take a desired shape.

Brief Description of the Drawings

Figs. 1A - 1B, and 1D are side elevations illustrating the construction of the transformable catheter of the present invention;

Fig. 1C is a top plan of the proximal portion of the transformable catheter of the present invention;

Fig. 1E is a view, similar to Fig. 1D but on an enlarged scale, illustrating the construction of a side port of the transformable catheter of the present invention;

Figs. 2A - 2D are simplified elevations illustrating some of the myriad shapes which are attainable with the transformable catheter of the present invention;

Figs. 3A - 3C are simplified elevations illustrating the reformation of a complex catheter shape inside the human body.

Figs. 4A - 4D are partial elevations illustrating operation of one embodiment of the present invention;

Fig. 5 is a partial elevation illustrating a gap shape different from that shown in Figs. 4A - 4D;

Fig. 6 is a view similar to Fig. 5 illustrating another gap shape;

Fig. 7 is a view similar to Fig. 4A illustrating an alternative construction;

Fig. 8 is a view similar to Fig. 4A showing a covering over the gaps;

Fig. 9 is a sectional view illustrating an alternative way to cause the catheter to bend in a desired direction;

Figs. 10 and 11 illustrate the method of construction of an alternative to that of Figs. 4A - 4D; and

Figs. 12 and 12A are perspective views illustrating an improved handle of the present invention.

Similar reference characters indicate similar parts throughout the several views of the drawings.

Description of the Preferred Embodiment

A catheter 31 (see Figs. 1A - 1C) of the present invention in its simplest form includes an enabling sheath 33, and an inner catheter 35 having a distal tip with a complex-curve shape.

Catheter 31 is especially suited for selective arterial catheterization. In that application, the catheter is custom shaped or formed while in the patient to make it easy to direct the tip in any orientation required to enter a branching orifice or serpiginous vessel. Catheter 31 is not a steerable catheter, but rather one which may be custom curved and recurved by the user to select each branch vessel. The catheter may also be used in the biliary tree and urinary tract to negotiate branches, corners, and serpiginous pathways.

As will become apparent in view of the following disclosure, manipulation of catheter 31 results in mimicking virtually any simple or complex curved configuration of selective arterial catheter shape imaginable while the catheter is disposed in the patient. Likewise, modification of curve and tip orientations allow selection and direction of wire guides for other invasive procedures such as percutaneous cholangiography and percutaneous nephrostomy; that is, any procedure requiring direction or redirection of a catheter.

Inner catheter 35 is a complex memory curve catheter which runs in a coaxial manner through enabling sheath 33. With the complex tip completely extended beyond the sheath, the most complex tip configuration reforms. By pulling the inner catheter back through the enabling sheath to varying degrees (sheathing and unsheathing the inner catheter tip), various segments of the curve are "ironed out" -- thereby changing the overall catheter tip configuration and tip orientation. The inner catheter is the active primary component but is a passive passenger with respect to the enabling sheath which acts upon the catheter to modify its shape. In addition, the fact that the transformation takes place in a vessel in the human body further modifies the shapes which can be achieved due to interaction of the transformable catheter with the walls of the vessel.

Sheath 33 has the capability of being formed by a pullwire 37 into a hook configuration, as described below. (Although described as a wire, item 37 could equivalently be made of high tensile strength suture or thread material.) This capability

allows reformation of the complex memory curvature by directing the catheter tip downward while transformable catheter 31 is disposed in the aorta. Secondly the sheath curve can, to some degree, act on the catheter to further modify the catheter shape.

In detail, transformable catheter 31 (see Figs. 1A - 1C) includes outer enabling sheath 33 which extends almost the entire length of the catheter. It is preferred that sheath 31 be long enough so that only the complex curve distal end portion of the inner catheter extends beyond it. Inner catheter 35 is disposed in the central bore of sheath 33 and has the most exaggerated sidewinder preformed tip configuration distally. (Of course, any other similar complex-shaped memory curve inner catheter could also be used in the present invention as inner catheter 35.)

The distal end of enabling sheath 33 can be formed into a curve with up to one hundred and eighty degrees of curvature when retracted by pull wire 37 by the suitable application of tension to the pull wire. This allows the hook configuration of the sheath 33 to reform the catheter 35 when the catheter is advanced through the sheath. The variable curved tip also allows variation in the degree of curvature, modifying the natural memory curve and thereby the overall shape of the catheter.

Enabling sheath 33 modifies the extreme natural curvature of catheter 35 by acting as a housing that irons out various segments of the curvature when the catheter is retracted back into the sheath. Such an "ironing" effect is illustrated in Fig. 2A. In Figs. 2 and 3, the various portions of transformable catheter 31 are shown in simplified form for clarity. For example, in Fig. 2A, the catheter 35 is shown extending distally from sheath 33 a small amount, while catheter and sheath are disposed in a vessel (such as an artery) 41.

In Fig. 2B, the same catheter 35 is shown extended distally out of sheath 33 a small additional amount such that the catheter regains some of its curvature. Similarly, in Figs. 2C and 2D, catheter 35 is extended distally even further. Note that in Fig. 2D, the distal curved portion of catheter 35 is fully extended from sheath 33, but the original configuration of catheter 35 is

not obtained because of the interaction of the catheter with vessel wall 41.

If the physician desires to instead shape or form catheter 35 back into its original, preformed shape of Fig. 1, the steps illustrated in Figs. 3A - 3C are followed. In this case, the sheath is first formed (by use of retraction wire 37) into the shape shown in Fig. 3A and Fig. 3B. As a result of this shape of the sheath, as catheter 35 is moved distally with respect to the sheath it assumes the form in the vessel as illustrated in Figs. 3A and 3B. The sheath is restraightened by suitable manipulation (i.e., release) of retraction wire 37 as shown in Fig. 3C as desired. This procedure allows the original form of catheter 35 to be obtained in the vessel.

Note, from comparing Fig. 2D with Fig. 3C, the great differences in catheter shape achievable by simple manipulation of sheath 33 and of the catheter with respect to the sheath. In fact Figs. 2A - 2D and 3A - 3C all illustrate some of the multitude of different catheter shapes which may be formed in the body, during a medical procedure, using the present invention. It should be realized that these shapes are merely illustrative and that with suitable manipulation of the sheath and relative movement between the sheath and the catheter, a great number of additional catheter configurations may be achieved.

Note as well, that the particular configuration shown in Fig. 3B provides a tighter radius for the tip of catheter 31 than is achievable with prior devices due to the interaction of the complex-formed tip of the inner catheter and the deflection of the sheath. This greater flexibility in the shapes achievable permits vessels to be entered with the present catheter which were not readily accessible with the prior devices.

Referring back to Figs. 1A - 1C, the inner catheter 35 travels through the enabling sheath in a coaxial manner, but is stiffened from its proximal end to a point just proximal to the distal exaggerated curvatures by an outer stiffening segment 43. This outer stiffening segment is fused to the inner catheter proximally and distally and provides sufficient strength to the

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inner catheter to permit it to be moved axially with respect to the sheath without collapsing or binding.

Transformable catheter 31 is introduced in the usual manner through the femoral artery and advanced into the abdominal aorta. The catheter is reformed and selectively shaped in the abdominal aorta. When initially introduced the inner catheter is in its ironed-out parked position within the enabling sheath with only a small distal tip segment protruding (see Fig. 2A). The pull wire 37 is retracted, forming a hooked curve (see Fig. 3A) which allows direction of the catheter tip downward and thereby easy reformation of the memory curve. Once reformed, the various shapes of the catheter can be selected by advancing or retracting the catheter into the enabling sheath, thereby allowing or disallowing the natural memory curves to form at various segments. Pull wire modification of the enabling sheath allows additional curved configurations.

Proximally, the stiffened inner catheter is pulled back through a plastic sleeve 45, slotted on either side. (See Figs. 1C and 1D.) A fixation collar 47 attaches to the proximal portion of the catheter. A molded spring "V" prong 49, rounded on one side and flat on the other, arises from the side of the collar and extends through the sleeve. The prong is fixedly secured to catheter 35 and can be pulled through a right slot 51 of the sleeve (see Fig. 1D), thereby pulling the catheter as a whole through the enabling sheath and ironing out various degrees of memory curve in the distal tip of the catheter. The spring "V" prong 49 when squeezed together passes freely through the slot whose border is straight inferiorly but serrated superiorly as shown in Fig. 1D. When released the prong springs open and the rounded segment locks in a chosen serrated position. Distally, a crossing slot 53 allows the prong to be pulled across to the left slot (similar in size and shape to the right slot 51 shown), thereby twisting and torquing the entire catheter one hundred and eighty degrees so that when the prong 49 is pulled back in the left slot position the curved configuration is ironed out, resulting in additional variations in catheter shape. The

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locking pattern of the left slot is opposite to that of the right -- flat upper border, serrated lower border, still allowing collar locking in various retracting positions.

The inner catheter proximally must exit through a valve (such as hemostasis valve 61 shown in Fig. 1C) as found in current arterial sheaths. A "Y" branch side port 63 allows constant pressure flushing of the sheath to prevent possible clot formation and allows water activation of the hydrophilic retraction wire.

On top of the side port 63, slide tracks 65 (see Fig. 1E) are molded. The tracks contain a plastic "S" spring slide 67 with locking teeth. The slide spring is attached to the pull wire 37 proximally. As the slide spring is disengaged by pushing downward and pulling back, the wire is retracted. When released the "S" slide locks into the selected position in the track. When straightening of the enabling sheath is desired, the slide 67 is disengaged and pushed to the forward position, thereby releasing traction on the wire and allowing the enabling sheath to reform spontaneously or with help by sliding the reinforced catheter towards the tip or by placing a straightening wire guide through the inner catheter lumen.

The ventral primary curvature segment of the enabling sheath is biased (as indicated at the reference numeral 71, Fig. 1A) to curve in a desired direction by making the sidewall along the inner portion of the desired curve more flexible due to the type or thickness of the material in this segment. Similarly, a flexibility bias can be established by designing exposed or covered gaps along one side of a segment of the sheath over which the bend is desired. When pulled distally, the more flexible or gapped side of the segment will give first, thereby, allowing curvature in a precisely selected segment and direction.

Although heretofore the invention has been described with respect to a transformable catheter with a controllable sheath and a complex curved inner catheter, the present invention is not so limited. The inventive aspects of the controllable sheath are applicable in general to medical tubing, including catheters. It

should be understood, therefore, that a reference herein to "sheath" should be understood in the broader sense of medical tubing, which includes catheters.

Turning to Fig. 4A, a sheath or catheter 72 of the present invention includes a medical tube 73 having an exterior wall and an internal lumen extending substantially through the length of the tube. The tube has an outside diameter sufficiently small so that it may be inserted into the human body. The distal end 74 of tube 73 is shown in Fig. 4A.

Wire 37 runs from the proximal end of the tube to the vicinity of the distal end of the tube, and, in the same manner as described above in connection with Fig. 1, is connected to the tube adjacent the distal end so as to allow the distal tip of the tube to be deflected upon movement of the wire. The tube has a substantially uniform transverse cross section throughout a substantial part of its length, except for the distal tip section. The tube wall adjacent the distal end has gaps 75, 77, and 79 therein on one side of the longitudinal axis of the catheter tube so as to form a predetermined region of weakness 71. As a result, upon tension being applied to the wire the distal end of the catheter tube bends in the direction of the predetermined region of weakness.

Although gaps 75, 77, and 79 can all be the same size, it is preferred that they differ in size as shown in Fig. 4A. The three gaps of Fig. 4A differ in depth, as can readily be seen. It has been found that with this construction the catheter or sheath preferentially bends first at the gap with the greatest depth (gap 79), and next at the gap with the second greatest depth (gap 77), and finally at the gap with the least depth (gap 75), as shown in Figs. 4B - 4D, as increasing tension is applied to wire 37.

Although gaps 75, 77 and 79 of Fig. 4 are generally crescent moon shaped, the present invention is not limited to any particular gap shape. For example, gaps 81 having a generally diamond shape (Fig. 5), or gaps 83 having a compound, arrowhead shape (Fig. 6), or any of a number of other gap shapes may also

be used. Gaps shaped so that portions of the catheter tube wall on opposite sides of each gap may overlap when the catheter is formed by the wire to have its greatest curvature may be used, as may gaps shaped so that there is no overlap (although overlapping can provide a tighter curve on the distal end of the sheath/catheter). Similarly, gaps shaped so that the distal wall portion overlaps the proximal wall portion of the gap when the catheter is formed by the wire to have its greatest curvature may be used, as may gaps shaped so that the proximal wall portion overlaps the distal wall portion of the gap.

Nor is there any rigid requirement concerning depth of gap. Although the gaps of Fig. 4 extend through the walls of the sheath/catheter to the lumen, that is not a requirement. In Fig. 7, for example, a gap 75A is provided which terminates short of the sheath/catheter lumen. It still helps provide the desired predetermined region of weakness 71. Also shown in Fig. 7 is a reinforcing section 85 which may, for example, be co-extruded with the sheath/catheter. This reinforcing section may be used in combination with the gaps, or by itself, to cause the distal end of the sheath/catheter to bend in the direction of region 71 when tension is applied to wire 37.

No matter what the shape of the gap, it is preferred that the inner surface of the gap adjacent the lumen of the catheter be smooth.

For some applications, it may be preferred that the gaps be covered. Fig. 8 shows a layer of material 87 covering the gaps. It should be realized that the physical appearance of layer 87 in Fig. 8 is illustrative only. The appearance will differ depending upon how layer 87 is made. It can be formed by dipping, fusing, or heat shrinking, for example.

Similarly, the gaps themselves may be formed in a number of different ways. They can be laser cut, water jet cut, punched, or formed by any other suitable procedure.

In addition, various ways can be used to form the predetermined region of weakness 71, either alone or in combination with the gaps. For example, Fig. 9 shows a region of

weakness 71 formed by reducing the thickness of the sheath/catheter wall at the predetermined region of weakness. Or, the predetermined region of weakness may be formed by having a portion of the wall which is chemically different from the tube wall elsewhere, or otherwise differs in some way from the rest of the sheath/catheter wall. This is accomplished, for example, by leaching material out of the appropriate portion of the sheath/catheter wall to form the region of weakness, or by using a different material in that region which is weaker than the material which makes up the rest of the sheath/catheter wall.

It should be appreciated that when gaps 75, 77 and 79 are cut into a straight sheath/catheter, and the layer 87 put over those gaps, there is the possibility that layer 87 material will bulge into the inner lumen of the sheath/catheter when the distal end is curved by application of tension to wire 37.

This bulging can be prevented if the distal end of the catheter tube is preformed into a curved shape with the gaps on the inner side of the preformed curve, as shown in Fig. 10. The gaps are then in their "rest" position when the distal end of the sheath/catheter is fully curved. A stretchable covering material 87 is then deposited over the gaps in this curved, "rest" position, so that the stretchable covering layer is substantially relaxed when the tube is disposed in a predetermined bent position.

With this construction, the stretchable covering layer 87 is substantially in tension when the distal end of the sheath/catheter is straight, and the covering layer tends to pull the distal end back to the preformed, curved shape. To overcome this tendency, a spring (or other suitable device) 91 is provided for biasing the stretchable covering layer into a stretched position, as shown in Fig. 11. A jacket of material 93 is provided to cover the biasing spring.

Turning to Figs. 12 and 12A, it is desirable to make the transformable catheter of the present invention as easy to use as possible. To facilitate this, a handle assembly 95 is provided which is an alternative to the structure shown in Figs. 1C - 1E.

Handle assembly 95 includes a handle 97 fixedly secured to sheath 33. Handle 97 has a slot 99 formed therein in which rides a thumbwheel operated clamp 101 (shown in more detail in Fig. 12A). The body of the thumbwheel operated clamp is connected to wire 37, so that the user may manually adjust the tension on wire 37 by moving clamp 101 to the desired position in slot 99 and fix the clamp in that position to maintain the desired tension on the wire. Since the position of clamp 101 in slot 99 is infinitely variable, the tension on wire 37 is also continuously variable over the desired range.

The construction of Fig. 12 also provides for infinite variation in the rotational and longitudinal positioning of catheter 35 with respect to handle 97. The handle has secured thereto a spring clamp 103. Catheter 35 may be held by the jaws of spring clamp 103 (or other suitable device) in any desired rotational or longitudinal position, as controlled by the user. The jaws of the clamp are merely opened to allow the user to move the catheter longitudinally and/or rotationally, and then closed on the catheter to hold it in the new desired position.

Also shown in Fig. 12 is an auxiliary line 105 which constitutes means (in combination with a syringe, for example) for forcing fluid between the sheath 33 and the catheter 35. Such flushing helps to prevent the formation of clots, for example.

In view of the above, it will be seen that the various objects and features of the present invention are achieved and other advantageous results obtained. The examples of the present invention disclosed herein are intended to be illustrative, and are not to be construed in a limiting sense.

WHAT IS CLAIMED IS:

1. A catheter comprising:

a catheter tube having a wall and an internal lumen extending substantially through the length of the catheter tube, said catheter tube having an outside diameter sufficiently small so that the catheter tube may be inserted into the human body, said catheter tube having a proximal end and a distal end;

at least one wire running from the proximal end of the catheter tube to the vicinity of the distal end of the catheter tube, said wire being connected to the catheter tube adjacent the distal end so as to allow the distal tip of the catheter tube to be deflected upon movement of said wire;

said catheter tube having a substantially uniform transverse cross section throughout a substantial part of its length, the catheter tube wall adjacent the distal end of the catheter tube having gaps therein on one side of the longitudinal axis of the catheter tube so as to form a predetermined region of weakness, whereby upon tension being applied to the wire the distal end of the catheter tube bends in the direction of the predetermined region of weakness formed by said gaps.

2. The catheter as set forth in claim 1 further including a layer of material covering said gaps which form the predetermined region of weakness.

3. The catheter as set forth in claim 1 wherein the gaps in the catheter tube wall are not all of the same size.

4. The catheter as set forth in claim 3 wherein the gaps of the different sizes differ in depth, whereby the catheter preferentially bends first at the gap with the greatest depth, and next at the gap with the second greatest depth.

5. The catheter as set forth in claim 1 wherein the gaps are shaped so that portions of the catheter tube wall on opposite sides of each gap may overlap when the catheter is formed by the wire to have its greatest curvature.

6. The catheter as set forth in claim 1 wherein at least some of the gaps extend through the catheter tube wall.

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7. The catheter as set forth in claim 6 wherein at least some of the gaps terminate short of the catheter lumen.

8. The catheter as set forth in claim 1 wherein the catheter tube wall thickness is reduced at the predetermined region of weakness.

9. The catheter as set forth in claim 1 wherein the catheter tube wall at the predetermined region of weakness is chemically different from the catheter tube wall elsewhere.

10. The catheter as set forth in claim 9 wherein the catheter tube wall at the predetermined region of weakness is formed of a material which differs from that of the rest of the catheter tube wall.

11. The catheter as set forth in claim 1 wherein a portion of the catheter tube wall transversely opposite the predetermined region of weakness is reinforced so as to cause bending to occur in the direction of the predetermined region of weakness when tension is applied to the wire.

12. The catheter as set forth in claim 1 wherein the distal end of the catheter tube is preformed into a curved shape with the gaps on the inner side of the preformed curve.

13. The catheter as set forth in claim 1 wherein the gaps are covered by a stretchable covering layer, said stretchable covering layer being substantially relaxed when the catheter tube is disposed in a predetermined bent position.

14. The catheter as set forth in claim 13 further including means for biasing the stretchable covering layer into a stretched position.

15. The catheter as set forth in claim 14 wherein the means for biasing includes a spring disposed about the distal end of the catheter tube.

16. The catheter as set forth in claim 15 further including a jacket of material covering said spring.

17. A transformable catheter comprising:

a sheath having a diameter sufficiently small so that the sheath may be inserted into blood vessels of the human body, said sheath having a length which is a substantial fraction of the

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entire length of the transformable catheter, and having a bore therethrough running substantially from the proximal end of the sheath to the distal end of the sheath;

a preformed inner catheter having a complex curve formed into the distal end thereof, said preformed catheter being sized to fit in the sheath bore and being axially movable with respect to the sheath in the bore, said sheath being sufficiently rigid and the inner catheter being sufficiently pliable so that withdrawal of the inner catheter into the sheath substantially irons out the portion of the complex curve of the distal tip disposed within the sheath, said distal tip resuming its complex curve shape upon movement thereof out of the sheath bore, said inner catheter having a length substantially corresponding to the length of the transformable catheter;

at least one wire running from the proximal end of the sheath to the vicinity of the distal end of the sheath, said wire being connected to the sheath adjacent the distal end so as to allow the distal tip of the sheath to be deflected upon movement of said wire;

whereby by suitable manipulation of the wire and of the inner catheter with respect to the sheath the shape of the exposed portion of the distal end of the inner catheter may be reformed and transformed to any of a variety of shapes as desired by the user;

said sheath having at its distal end a predetermined region of weakness so that upon tension being applied to the wire, the distal end of the sheath bends in the direction of the predetermined region of weakness.

18. The transformable catheter as set forth in claim 17 wherein the sheath wall thickness is reduced at the predetermined region of weakness.

19. The transformable catheter as set forth in claim 17 wherein the sheath wall at the predetermined region of weakness is chemically different from the sheath wall elsewhere.

20. The transformable catheter as set forth in claim 19 wherein the sheath wall at the predetermined region of weakness

is formed of a material which differs from that of the rest of the sheath.

21. The transformable catheter as set forth in claim 17 wherein a portion of the sheath wall transversely opposite the predetermined region of weakness is reinforced so as to cause bending to occur in the direction of the predetermined region of weakness when tension is applied to the wire.

22. The transformable catheter as set forth in claim 17 wherein the sheath wall adjacent the distal end of the sheath has gaps therein on one side of the longitudinal axis of the sheath so as to form said predetermined region of weakness, whereby upon tension being applied to the wire the distal end of the sheath bends in the direction of the predetermined region of weakness.

23. The transformable catheter as set forth in claim 22 further including a layer of material covering said gaps which form the predetermined region of weakness.

24. The transformable catheter as set forth in claim 22 wherein the gaps in the sheath wall are not all of the same size.

25. The transformable catheter as set forth in claim 24 wherein the gaps in the sheath wall are of at least three different sizes.

26. The transformable catheter as set forth in claim 25 wherein the gaps of the different sizes differ in depth, whereby the sheath preferentially bends first at the gap with the greatest depth, and next at the gap with the second greatest depth.

27. The transformable catheter as set forth in claim 22 wherein the gaps are shaped so that portions of the sheath wall on opposite sides of each gap may overlap when the sheath is formed by the wire to have its greatest curvature.

28. The transformable catheter as set forth in claim 22 wherein at least some of the gaps extend through the sheath wall.

29. The transformable catheter as set forth in claim 28 wherein at least some of the gaps terminate short of the sheath bore.

30. The transformable catheter as set forth in claim 22 wherein the distal end of the sheath is preformed into a curved shape with the gaps on the inner side of the preformed curve.

31. The transformable catheter as set forth in claim 22 wherein the gaps are covered by a stretchable covering layer, said stretchable covering layer being substantially relaxed when the sheath is disposed in a predetermined bent position.

32. The transformable catheter as set forth in claim 31 wherein said stretchable covering layer disposed over said gaps is substantially in tension when the distal end of the sheath is substantially straight.

33. The transformable catheter as set forth in claim 22 further including means for biasing the stretchable covering layer into a stretched position.

34. The transformable catheter as set forth in claim 33 wherein the means for biasing includes a spring disposed about the distal end of the sheath.

35. The transformable catheter as set forth in claim 34 further including a jacket of material covering said spring.

36. The transformable catheter as set forth in claim 17 further including manually adjustable means for maintaining a desired tension on the wire.

37. The transformable catheter as set forth in claim 36 wherein means for maintaining a desired tension on the wire includes a handle fixedly secured to the sheath and a manually operable member attached to the wire, said member being longitudinally movable with respect to the handle to change the tension of the wire, and being manually fixable with respect to the handle at a plurality of locations to maintain the tension of the wire at a plurality of different values.

38. The transformable catheter as set forth in claim 37 wherein the catheter is movable rotationally and longitudinally with respect to the handle, further including manually operable means for fixing the catheter in any desired rotational and/or longitudinal position with respect to the handle.

39. The transformable catheter as set forth in claim 38 wherein the means for fixing the catheter in position with respect to the handle includes a manually operable clamp attached to the handle, said second manually operable clamp being adapted to hold the catheter against both longitudinal and rotational movement with respect to the handle.

40. The transformable catheter as set forth in claim 17 wherein the catheter is movable rotationally and longitudinally with respect to the sheath, further including manually operable means for fixing the catheter in position with respect to the handle.

41. The transformable catheter as set forth in claim 40 wherein the means for fixing the catheter in position with respect to the handle includes a manually operable clamp attached to the handle, said manually operable clamp being adapted to hold the catheter against both longitudinal and rotational movement with respect to the handle.

42. A transformable catheter comprising:

a sheath having a diameter sufficiently small so that the sheath may be inserted into the human body, said sheath having a length which is a substantial fraction of the entire length of the transformable catheter, and having a bore therethrough running substantially from the proximal end of the sheath to the distal end of the sheath;

a preformed inner catheter having a complex curve formed into the distal end thereof, said preformed catheter being sized to fit in the sheath bore and being axially movable with respect to the sheath in the bore, said sheath being sufficiently rigid and the inner catheter being sufficiently pliable so that withdrawal of the inner catheter into the sheath substantially irons out the curve of that portion of the distal tip which is disposed in the sheath, said distal tip resuming its complex curve shape upon movement thereof completely out of the sheath bore, said inner catheter having a length substantially corresponding to the length of the transformable catheter, said complex curve having at least three curve portions having

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different radii of curvature, at least one of said curve portions having a direction of curvature retrograde to that of at least two of the other curve portions;

at least one wire running from the proximal end of the sheath to the vicinity of the distal end of the sheath, said wire being connected to the sheath adjacent the distal end so as to allow the distal tip of the sheath to be deflected upon movement of said wire;

whereby by suitable manipulation of the wire and of the inner catheter with respect to the sheath the shape of the exposed portion of the distal end of the inner catheter may be reformed and transformed to any of a variety of shapes as desired by the user.

43. The transformable catheter as set forth in claim 42 wherein the sheath includes at its distal end a predetermined region of weakness so that upon tension being applied to the wire, the distal end of the sheath bends in the direction of the predetermined region of weakness.

44. The transformable catheter as set forth in claim 43 wherein upon removal of the tension from the wire, the sheath attempts to return to its original shape.

45. The transformable catheter as set forth in claim 42 wherein the distal tip of the inner catheter is substantially more pliable than the body of the inner catheter, whereby the inner catheter has sufficient strength to support axial and rotational movement thereof with respect to the sheath.

46. The transformable catheter as set forth in claim 42 further including means for holding the inner catheter longitudinally in place with respect to the sheath at a plurality of positions.

47. The transformable catheter as set forth in claim 46 wherein the means for holding the inner catheter longitudinally in place with respect to the sheath at a plurality of positions includes means for mechanically locking the inner catheter in place with respect to the sheath, said means for mechanically locking being manually operable to unlock the inner catheter with

respect to the sheath for longitudinal movement with respect thereto.

48. The transformable catheter as set forth in claim 47 wherein the means for mechanically locking includes a slot and pin locking mechanism.

49. The transformable catheter as set forth in claim 42 further including mechanical means for locking the inner catheter in at least two different rotational positions with respect to the sheath, said mechanical means for locking being manually operable for unlocking the inner catheter with respect to the sheath for movement to another rotational position with respect thereto.

50. The transformable catheter as set forth in claim 42 further including means for rotating the inner catheter with respect to the sheath.

51. The transformable catheter as set forth in claim 42 wherein the distal end of the sheath is tapered so as to reduce the diameter of the distal end of the sheath to a diameter approximating the diameter of the inner catheter.

52. The transformable catheter as set forth in claim 42 wherein the sheath includes a lumen extending substantially from the proximal to the distal end thereof in which the wire is disposed.

53. The transformable catheter as set forth in claim 42 wherein there is only one wire running from the proximal end of the sheath to the vicinity of the distal end of the sheath.

54. The transformable catheter as set forth in claim 42 further including means for holding the wire longitudinally in place with respect to the proximal end of the sheath at a plurality of relative positions to selectively apply a plurality of different tensions, as desired by the user, to the wire, said holding means including mechanical means for locking the wire longitudinally in place, said mechanical means being manually operable to release the tension on the wire.

55. A method of changing the shape of a catheter in a human body, comprising the steps of:

inserting a combination catheter into a cavity of a human body, said combination catheter having a sheath with a length which is a substantial fraction of the entire length of the combination catheter, said combination catheter also having a preformed inner catheter with a complex curve formed into the distal end thereof disposed in the bore of the sheath, said preformed inner catheter extending distally from the distal end of the sheath during insertion into the human body;

axially moving the inner catheter with respect to the bore to expose only so much of the distal end of the inner catheter as to cause the exposed portion of the distal end of the inner catheter to take a desired shape, wherein the distal end of the inner catheter can take a plurality of shapes depending upon the amount of the distal end which is exposed; and

deflecting the distal end of the sheath to direct the distal end of the inner catheter in any of a plurality of desired directions and to attain a plurality of shapes.

56. The method of changing the shape of a catheter in a human body as set forth in claim 55 wherein the shape of the distal end of the inner catheter is affected by contact with the wall of the cavity in which the catheter is disposed.

57. The method of changing the shape of a catheter in a human body as set forth in claim 55 wherein the deflecting step includes deflecting the distal end of the sheath in a direction such that the preformed complex curve of the distal end of the inner catheter may be reformed inside the human body, and extending the distal end of the inner catheter distally out of the sheath to reform the complex curve of the distal end of the inner catheter inside the human body.

58. The method of changing the shape of a catheter in a human body as set forth in claim 55 wherein the distal end of the sheath is deflected and the distal tip of the inner catheter is exposed in an amount to cause the distal end of the combination catheter to assume a radius smaller than the radius achievable by deflecting the distal end of the sheath alone.

59. The method of changing the shape of a catheter in a human body as set forth in claim 55 wherein the distal end of the sheath is deflected by selectively applying tension to a wire disposed in the sheath.

60. The method of changing the shape of a catheter in a human body as set forth in claim 55 further including the step of rotating the inner catheter with respect to the sheath to further change the possible shapes of the combination catheter.

61. The method of changing the shape of a catheter in a human body as set forth in claim 55 further including the step of at least temporarily fixing the inner catheter in place with respect to the sheath when the desired shape is achieved.

62. The method of changing the shape of a catheter in a human body as set forth in claim 55 wherein the combination catheter is formed into a plurality of distinct shapes in the human body during a single medical procedure.

63. The method of changing the shape of a catheter in a human body as set forth in claim 62 comprising forming the combination catheter into the plurality of distinct shapes in the human body during a single medical procedure to catheterize all the vessels necessary for a cerebral arteriogram.

64. The method of changing the shape of a catheter in a human body as set forth in claim 62 wherein during a single medical procedure the combination catheter is formed into a shape having a first distal configuration, a first vessel is catheterized while the combination catheter is in the first shape, the combination catheter is formed into a second shape having a second distal configuration, and a second vessel is catheterized while the combination catheter is in the second shape, said first distal configuration having at least one less radii of curvature than the second distal configuration, the distal tip of the combination catheter in the first distal configuration pointing substantially opposite the direction of the distal tip of the combination catheter in the second distal configuration.

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65. A transformable catheter comprising:

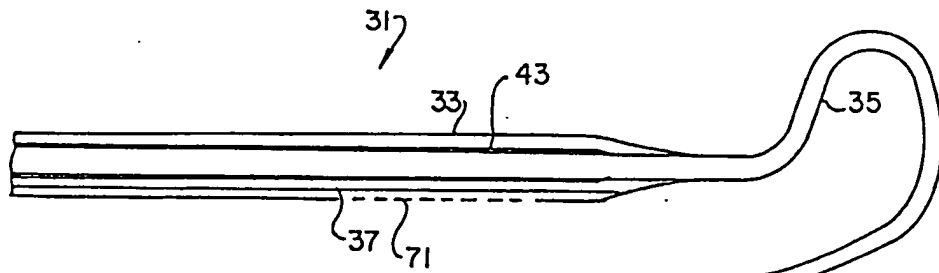
a sheath having a diameter sufficiently small so that the sheath may be inserted into the human body, said sheath having a length which is a substantial fraction of the entire length of the transformable catheter, and having a bore therethrough running substantially from the proximal end of the sheath to the distal end of the sheath;

a preformed inner catheter having a complex curve formed into the distal end thereof, said preformed catheter being sized to fit in the sheath bore and being axially movable with respect to the sheath in the bore, said sheath being relatively rigid with respect to the inner catheter and the inner catheter being relatively pliable with respect to the sheath so that manipulation of the sheath results in corresponding manipulation of the inner catheter, said inner catheter having a length substantially corresponding to the length of the transformable catheter;

at least one wire running from the proximal end of the sheath to the vicinity of the distal end of the sheath, said wire being connected to the sheath adjacent the distal end so as to allow the distal tip of the sheath to be deflected upon movement of said wire;

said sheath having gaps therein on one side of the sheath to form a predetermined region of weakness so that upon tension being applied to the wire, the distal end of the sheath bends in the direction of the predetermined region of weakness.

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X FIG. 1A.

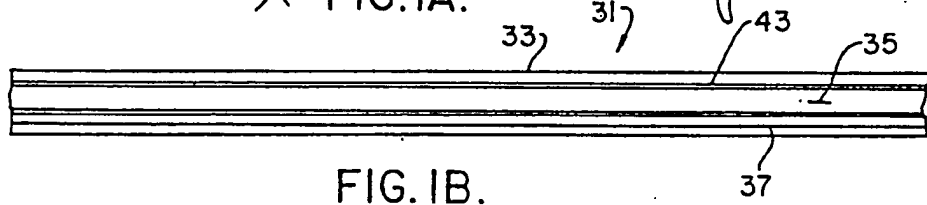


FIG. 1B.

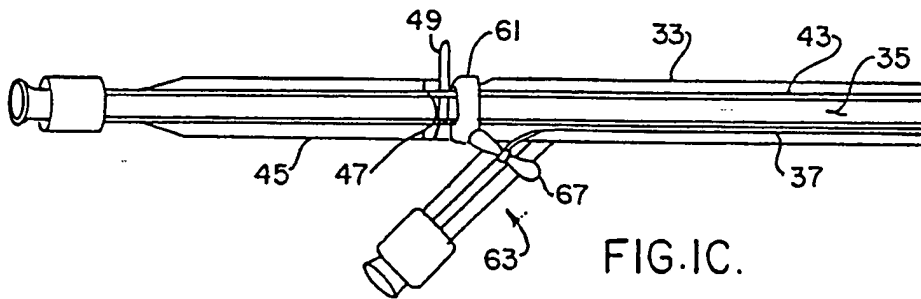


FIG. 1C.

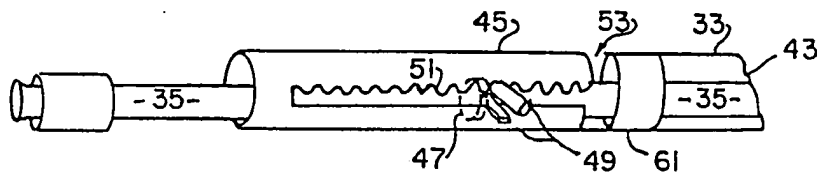


FIG. 1D.

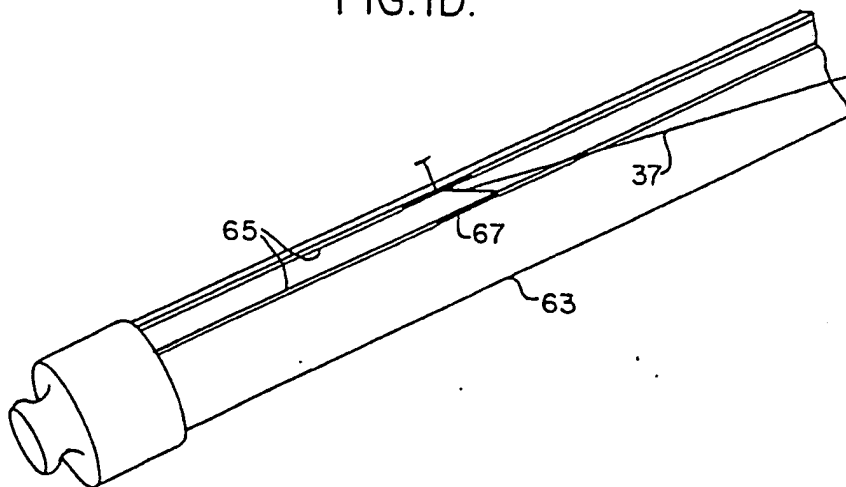


FIG. 1E.

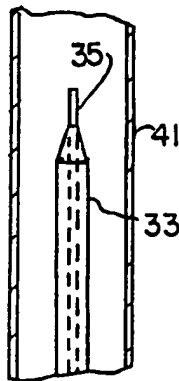


FIG. 2A.

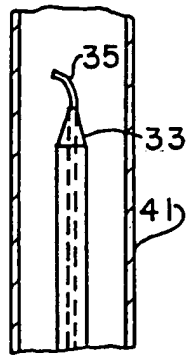


FIG. 2B.

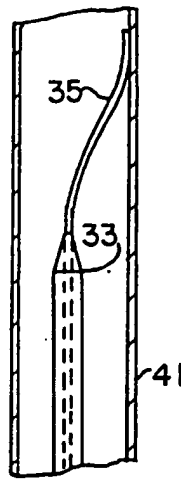


FIG. 2C.

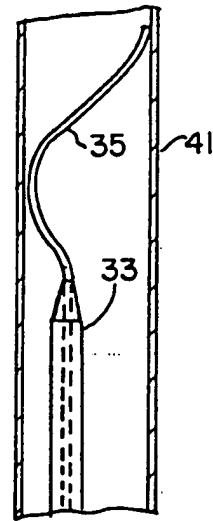


FIG. 2D.

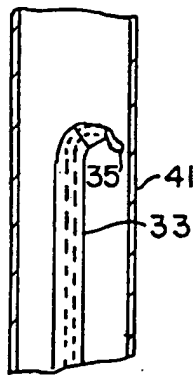


FIG. 3A.

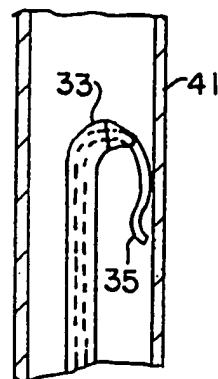


FIG. 3B.

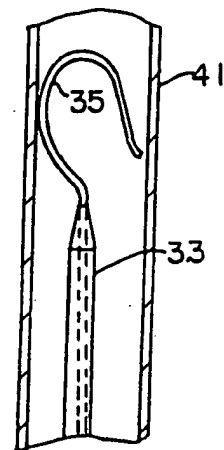


FIG. 3C.

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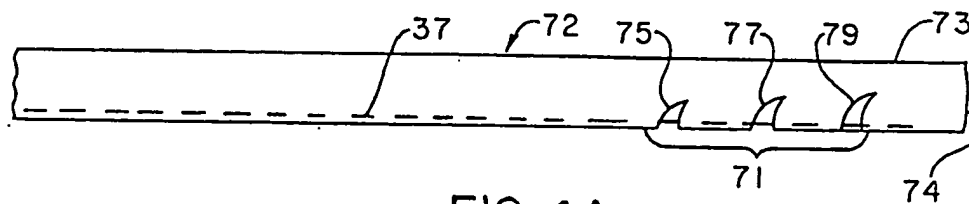


FIG. 4A.

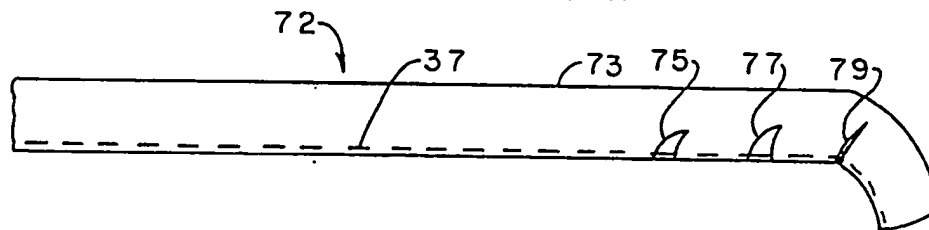


FIG. 4B.

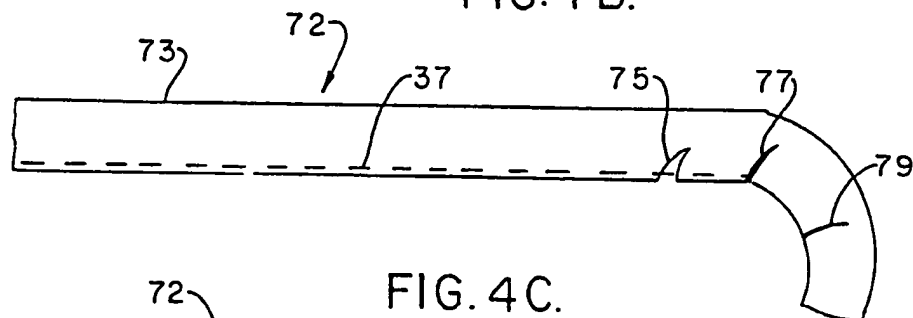


FIG. 4C.

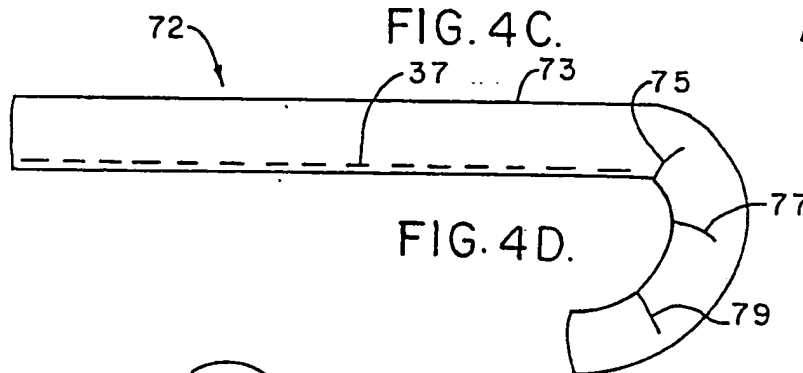


FIG. 4D.

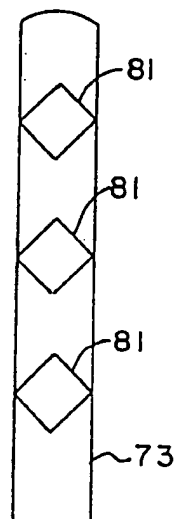


FIG. 5.

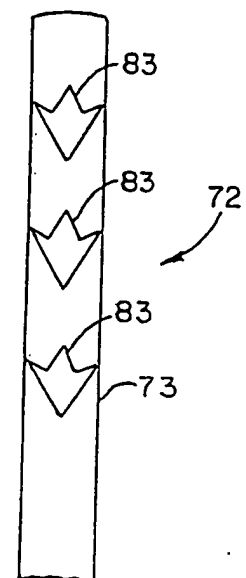
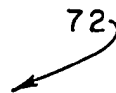


FIG. 6.

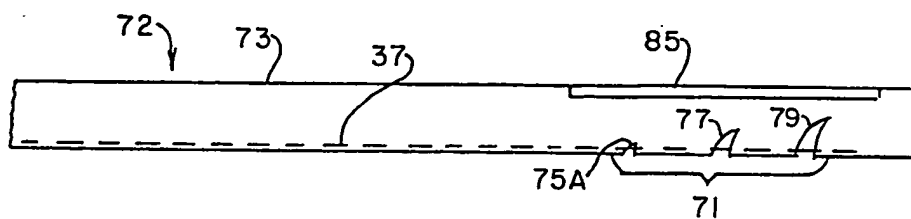


FIG. 7.

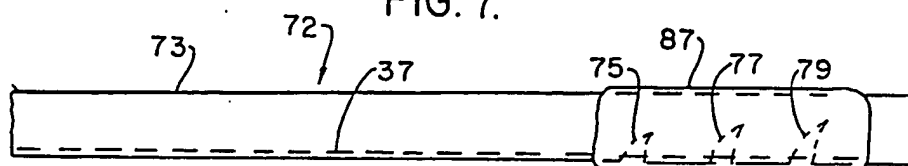


FIG. 8.

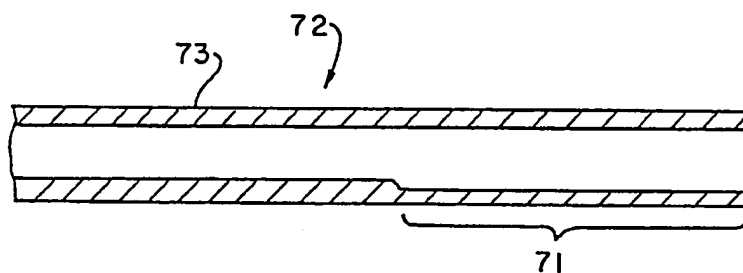


FIG. 9.

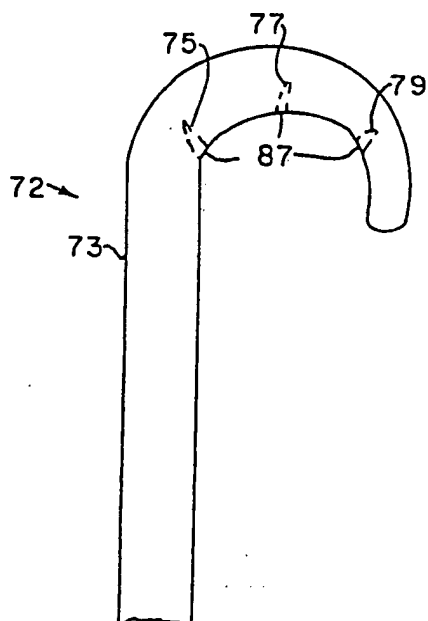


FIG. 10.

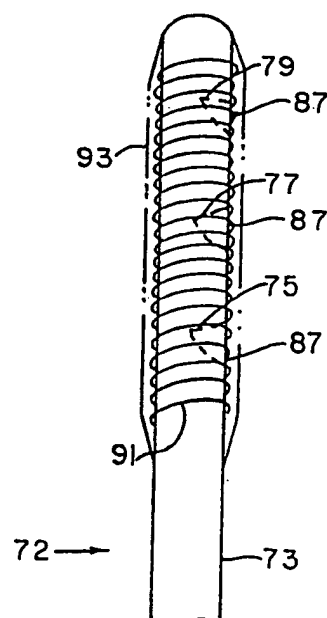


FIG. 11.

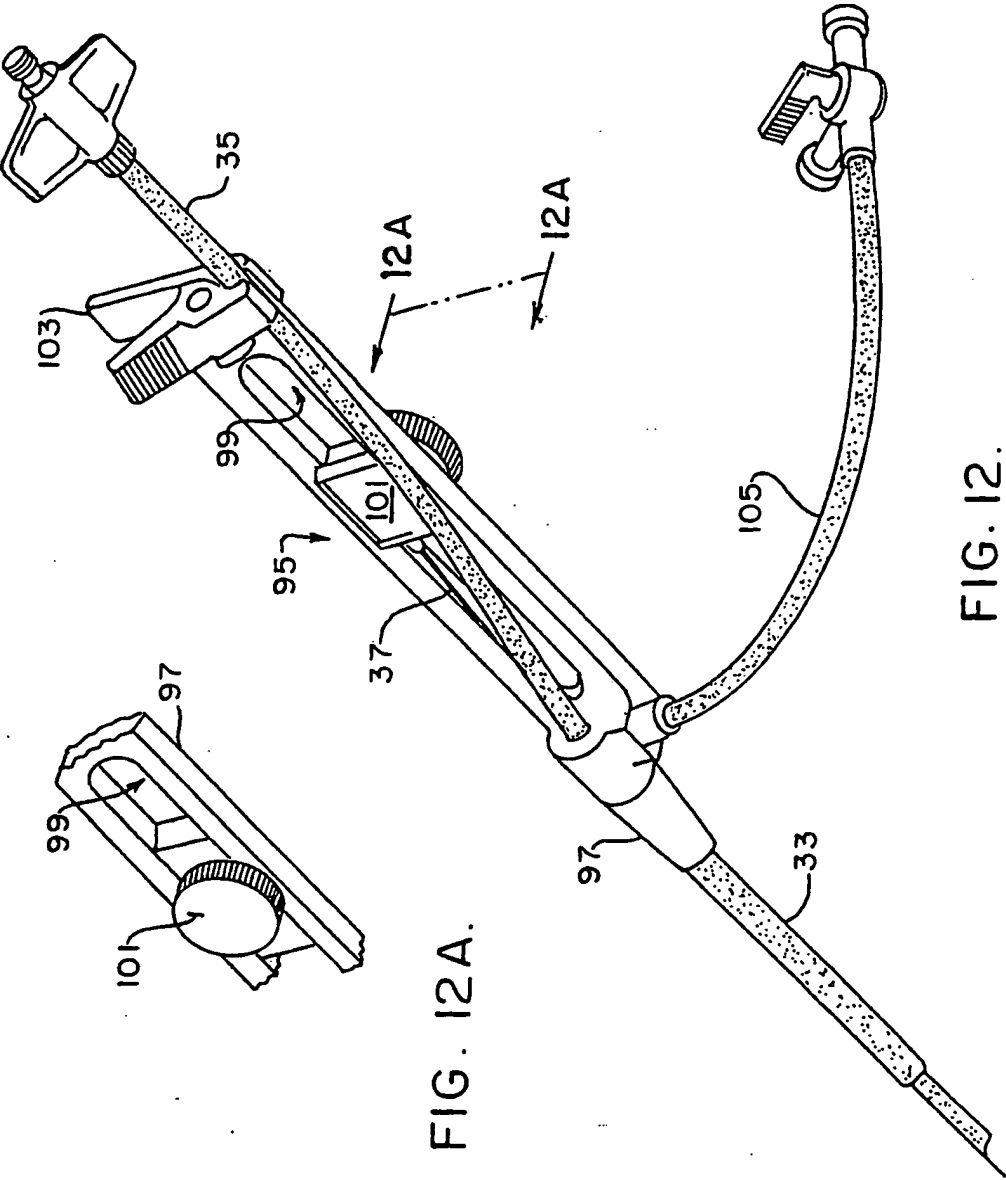


FIG. 12A.

FIG. 12.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/05833

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 37/00

US CL :604/95

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/95,280,281; 128/4,656-658,772

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US, A, 4,911,148 (SOSNOWSKI ET AL.) 27 March 1990, See entire document.	<u>1-15</u> 22-33,65
X	US, A, 4,935,017 (SYLVANOWICZ) 19 June 1990, See entire document.	<u>55-58</u> 17-47,49-54, 59-65
Y	DE, A, 2,923,633 (RENTROP) 18 December 1980, See entire document.	17-33
Y	US, A, 4,898,577 (BADGER ET AL.) 06 February 1990, See entire document.	17-47,49-54, 59-65
X	US, A, 4,807,626 (McGIRR) 28 February 1987, See figs. 20A-23.	55-58

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 05 OCTOBER 1992	Date of mailing of the international search report 15 DEC 1992
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer MARK BOCKELMAN Telephone No. (703) 308-2112

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/05833

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
<u>X</u>	US, A, 4,236,509 (TAKAHASHI ET AL.) 02 December 1980,	<u>15,16</u>
Y	See entire document.	34,35
X	US, A, 4,353,358 (EMERSON) 12 October 1982, See entire document.	1-2,5-14